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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,715	08/20/2003	George V. Guittard	AR02366USACON3	8447

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EXAMINER	
GEORGE, KONATA M	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 04/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/645,715	GUITTARD ET AL.	
	Examiner	Art Unit	
	Konata M. George	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *40-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/26/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 40-48 are pending in this application.

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on January 26, 2006 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

Action Summary

2. The rejection of claims 40, 41, 44, 45 and 48 under 35 U.S.C. 102(a) over Rantala is hereby withdrawn with respect to applicants' arguments of the priority date of the instant invention and the prior art.

3. The rejection of claims 42, 43, 46 and 47 under 35 U.S.C. 102(a) over Rantala in view of Enomoto et al. is hereby withdrawn with respect to applicants' arguments of the priority date of the instant invention and the prior art.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 40-47 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3 and 4 of U.S. Patent No. 5,674,895. Although the conflicting claims are not identical, they are not patentably distinct from each other because the pending application is directed towards a dosage form comprising oxybutynin or its pharmaceutically acceptable salt in a dosage amount of 5 mg to 250 mg and a hydroxypropylalkylcellulose and the '895 patent teaches a composition comprising 1ng to 450 mg of oxybutynin and a hydroxypropylalkylcellulose. It is the position of the examiner that since the both the pending application and the patent contain administering oxybutynin having overlapping dosage ranges, it would have been obvious to one of ordinary skill in the art to add excipients to the dosage form of the pending application to help facilitate the production and delivering of the drug.

5. Claims 40 and 48 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 5,840,754. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the pending application and the '754 patent are directed toward a method reducing the incidence of side effects associated with oxybutynin treatment by administering the drug over a twenty-four hour period.

The difference between the pending application and the '754 patent is the recitation of a dosage amount and the delivery form as a tablet. It is the position of the examiner that the dosage amount is a limitation that would be routinely determined by one of ordinary skill in the art as part of the process of normal optimization to achieve the desired results of reducing the incidence of side effects associated with oxybutynin treatment.

6. Claims 40-47 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 5,912,268. Although the conflicting claims are not identical, they are not patentably distinct from each other because the pending application is directed towards a dosage form comprising oxybutynin or its pharmaceutically acceptable salt in a dosage amount of 5 mg to 250 mg and the '268 patent also teaches a dosage form comprising oxybutynin or its pharmaceutically acceptable salt contained in a dosage amount of 240 ng to 650 mg. The dosage form also contains hydroxypropylalkylcellulose and polyalkylene oxide. It is the position of the examiner that since the pending application and the patent are directed towards the same invention then it is not patentability distinct from each other. Although the claims of the prior art do not explicitly say a tablet as the dosage form, it is described in the claims with the teaching of a wall that surrounds a drug core.

Response to Arguments

7. Applicants' are advised that the above double patenting rejections where made in the office action dated July 22, 2004. The claims have been changed with respect to amendments filed during the prosecution of the application. Because the claims have changes in some instances a final rejection will not be made although the rejections were made in a previous office action.

Conclusion

8. Claims 40-48 are rejected.

Telephone Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is (571) 272-0613. The examiner can normally be reached from 8AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (571) 272-0887. The fax phone numbers for the organization where this application or proceeding is assigned are (571) 273-8000 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Konata M. George

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER